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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,743	11/21/2000	Rajesh Ranganathan	01997/521003	1951

7590 10/22/2002

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/22/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. <b>09/717,743</b>	Applicant(s) <b>Ranganathan et al.</b>
	Examiner <b>Joseph T. Woitach</b>	Art Unit <b>1632</b>
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p> <p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>		
<b>Status</b>		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jul 29, 2002</u>		
2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-21</u> is/are pending in the application.		
4a) Of the above, claim(s) <u>2, 4, 6-15, and 17-21</u> is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1, 3, 5, and 16</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input checked="" type="checkbox"/> The drawing(s) filed on <u>Nov 21, 2000</u> is/are <u>a</u> <input checked="" type="checkbox"/> accepted or <u>b</u> <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: <u>a</u> <input type="checkbox"/> approved <u>b</u> <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b>		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3, 10</u>		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

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## **DETAILED ACTION**

This application filed November 21, 2000, is a continuation in part of application 09/559,622, filed April 27, 2000, which claims benefit to 60/131,149, filed April 27, 1999.

### ***Election/Restriction***

Applicant's election without traverse of group I, claims 1, 3, 5 and 16 in Paper No. 11 is acknowledged.

Claims 1-21 are pending. Claims 2,4, 6-15 ad 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11. Claims 1, 3, 5 and 16 are currently under examination as they are drawn to a substantially pure nucleic acid sequence encoding a serotonin-gated anion channel.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

Claim 16 is objected to because of the following informalities:

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As noted in the restriction requirement, claim 16 as written is dependent on claim 85, however there is no claim 85 pending. It appears that claim 16 is drawn to embodiments in claim 15, and for compact prosecution claim 16 will be considered dependent on claim 15. If claim 16 is dependent on claim 15, it would be dependent on a non-elected claim. In any case rewriting the claim as an independent to include all the embodiments of the intended claim or non-elected claim would obviate the objection.

Appropriate correction is required.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3, 5 and 16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 5, and 16 of copending Application No.09/559,622. In the

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instant case, the claims are exact duplicates of each other. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Olde *et al.*, Ramamoorthy *et al.*, Demchyshyn *et al.*, Corey *et al.* or Blakely *et al.* (each present in the IDS).

Claim 1 is drawn broadly to a nucleic acid sequence encoding serotonin-gated anion channel. Dependent claims 3 recites that the anion channel is a chloride channel, and claim 5 recites that the sequence is MOD-1. In the summary of the invention MOD-1 is described as a serotonin-gated ion channel (page 4; line 8). Though the specification describes specific polynucleotide sequences termed MOD-1, the specification also describes other forms of the anion channel including sequences from other animal sources, and a variant or mutant of the 5HT receptor (pages 5-7), therefore this term is given its broadest reasonable interpretation encompassing a serotonin-gated anion channel. Olde *et al.*, Ramamoorthy *et al.*, Demchyshyn *et*

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*al.* and Blakely *et al.* each teach the cloning and characterization of serotonin anion channel.

Olde *et al.* describes the polynucleotide sequence isolated from *C. elegans* (figure 1) and compares the sequence to other known serotonin channels (figure 2), Ramamoorthy *et al.* describes the isolation and characterization of a human serotonin channel (figure 3) and provides a potential chromosomal location (figure 4), Demchyshyn *et al.* and Corey *et al.* describes the isolation and characterization of a Drosophila serotonin channel (figure 1 and figure 2, respectively), and Blakely *et al.* describes the isolation and characterization of a rat serotonin channel (figure 3). Each of these share homology to each other and are related as they are identified as serotonin gated chloride channels (see abstracts of Demchyshyn *et al.*, Corey *et al.* and Ramamoorthy *et al.* and summary of 5-HTs in Olde *et al.* for example). In light of the breadth of the present claims which encompass any serotonin-gated chloride anion channel, the polynucleotide sequences taught by Olde *et al.*, Ramamoorthy *et al.* and Blakely *et al.* meet the limitations of the claims and thus, anticipate claims 1, 3 and 5.

With respect to claim 16, drawn to an isolated gene identified by a method for isolating genes related to serotonin gated anion channels, because no specific method or sequence used in the identification of a serotonin gene is set forth in the claim, a reasonable interpretation of claim 16 encompasses any serotonin gated related sequence, including a cDNA sequence. Since each of the sequences disclosed in Olde *et al.*, Ramamoorthy *et al.*, Demchyshyn *et al.*, Corey *et al.* and Blakely *et al.* are cDNA sequences encoding a serotonin gated anion channel, the

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polynucleotide sequences taught by Olde *et al.*, Ramamoorthy *et al.* and Blakely *et al.* meet the limitations of the claim and thus, anticipates claim 16.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Segalat *et al.* (IDS reference).

Claim 16 is drawn to an isolated gene identified by a method for isolating genes related to serotonin gated anion channels. Please note, as indicated above, for the sake of compact prosecution, claim 16 is being interpreted as being dependent on claim 15. When interpreting a product by process, it is noted that the office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). In the instant case, no specific method or sequence used in the identification of a serotonin gene is set forth in the claim, therefore given the broadest reasonable interpretation, claim 16 encompasses any serotonin gated related gene. Segalat *et al.* describes the identification of a genomic fragment encompassing the goa-1 gene (figure 1). which when deleted in *C. elegans* affects the behavior consistent with behavioral effects of 5-HT

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(i.e. serotonin). Since this gene is related to serotonin-gated anion channels, it meets the limitation of claim 16, and thus anticipates the claim.

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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